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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,392	07/23/2003	Stefan Assmann	P03,0017	9086

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EXAMINER	
SOLANKI, PARIKHA	
ART UNIT	PAPER NUMBER
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,392	ASSMANN ET AL.	
	Examiner	Art Unit	
	Parikha Solanki	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges Applicant's amendment to claim 1-16 as being sufficient to cure the statutory deficiencies set forth in the prior Office Action, and as such the rejection of these claims under 35 U.S.C. § 101 is withdrawn.

Examiner additionally acknowledges Applicant's amendment to claim 33 as being sufficient to overcome the previous rejection of this claim under 35 U.S.C. § 112, 2nd paragraph, as set forth in the prior Office Action. Accordingly, this rejection is withdrawn.

Response to Arguments

2. Applicant contends that the Prince reference does not anticipate the invention of claims 1-3-5, 7, 15 and 16. With regards to the argument that Prince does not disclose imaging a cross-section of the blood vessel, Examiner respectfully directs Applicant's attention to the definition of the term "cross-section" as set forth by Merriam Webster (http://www.m-w.com):

> Main Entry: **cross section**
> Function: *noun*
> **1 a :** a cutting or piece of something cut off at right angles to an axis; *also* **:** a representation of such a cutting **b : SECTION** 3b

In light of this definition, the Prince reference does, in fact, implicitly disclose imaging of a cross-section, as one may interpret a longitudinal representation of the vessel to constitute a cross-section. While Applicant's amendment to claim 1 to make clear that the cross-section is transverse overcomes this discrepancy, the new grounds of rejection presented below further obviate this limitation.

Additionally, Applicant contends that, in the Prince reference, "there is no disclosure or suggestion of the contrast agent interacting with plaque." Examiner respectfully directs Applicant's attention to the specification of the instant application, which provides no detail to describe the specific nature of the interaction between the plaque and the contrast agent. By the definition of the word "interact" as set forth by Merriam Webster (http://www.m-w.com), which is provided below, the contrast agent of Prince does indeed interact with the plaque, in that it comes in contact with such plaque over the course of it traversal of the blood vessel lumen.

> Main Entry: **in·ter·act**

Pronunciation: "in-t&r-'akt
Function: *intransitive verb*
: to act upon one another

Furthermore, the specification specifically states "the known contrast agent Gd-DTPA is employed as the contrast agent." As previously set forth in the prior Office Action, Prince explicitly discloses Gd-DTPA as the contrast agent used during the imaging method (Fig. 1). As such, Examiner maintains that Prince discloses the use of a contrast agent which interacts with plaque as claimed in the instant application.

Regarding Applicant's additional arguments concerning the merits of the Prince, Cai and Clark references as applied to claims 1-33, such arguments have been considered, but are moot in view of the new grounds of rejection presented below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-7, 9-23 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (Identification of atherosclerotic plaque components using cluster analysis of multispectral MR images: comparison with histology. *Proc. SPIE Int. Soc. Opt. Eng.* 3978, 304-311. April 2000) in view of Prince (US Patent No. 5,579,767).

Clarke (2000) teaches means and steps for automatically classifying atherosclerotic plaque based on composition in order to assess a patient's risk of stroke, equivalent to propensity for dislodgement as claimed in the instant application (Abstract). Clarke (2000) teaches the use of a maximum likelihood classification algorithm, which evaluates signal intensity on a pixel by pixel basis across a series of images (p. 306, Fig. 1), in order to provide for an automated method of analyzing transverse cross-sectional MR images of the blood vessel (Fig. 1). The algorithm of Clarke (2000) employs multispectral analysis to assess the material present in the region. It is well known that spectral analysis and intensity distribution both quantify the amount of a specific type of material present in an image. The algorithm of Clarke (2000) calculates signal intensity on a pixel by pixel basis and further analyzes the intensities

across a series of images of the same region, which is equivalent to forming intensity distributions of the cross-sectional images as claimed in the instant application (Fig. 1). Furthermore, the computer of Clarke (2000) classifies plaque according to presence of fibrous plaque, calcification, cholesterol, fibrin, cellular plaque and intraluminal thrombus (p. 306 ¶2).

Although Clarke (2000) is silent with respect to classification by small vessel formation, such a class is known in the art and would be obvious to one of ordinary skill in the art at the time of invention. Furthermore, although Clarke (2000) does not expressly mention presenting the classification result in a visually perceptible display at the computer, this step is implicitly taught by the reference, as it is obvious that a computer algorithm cannot be usefully executed without displaying the results.

Clarke (2000) fails to provide means and steps for injection of a contrast agent. Additionally, Clark (2000) does not teach means and steps for acquiring three images, the timing of the acquisition being correlated to the phase of contrast agent uptake.

In the same field of endeavor, Prince ('767) teaches a system and method of arterial MR imaging for detecting, examining and grading occlusive lesions, which are equivalent to arterial plaque or atheroma (Abstract, col. 17 line 31, col. 6 line 53, col. 8 line 29, col. 4 line 59, Fig. 9, col. 5 line 62). Specifically, Prince ('767) teaches means and steps for collecting an initial baseline MR image (col. 5 line 33), injecting a gadolinium-based contrast agent such as Gd-DTPA into the subject (Figs. 1 & 5A), and collecting several contrast-enhanced MR images following injection (col. 5 line 43). Although Prince ('767) does not explicitly state that the contrast injection is controlled by a computer, the reference does state that the agent is administered to the patient "at a controlled rate over a period of time." Automating such a manual task is not sufficient to distinguish the present invention over the prior art, and is thereby considered obvious. For further detail regarding the obviousness of automating manual tasks, see MPEP section 2144 III.

Regarding the timing of image acquisition relative to contrast injection, Prince ('767) teaches the collection of image data at the time of elevated arterial contrast, equivalent to the enrichment phase (col. 6 line 53). Prince ('767) teaches that such a time occurs between 10 and 50 seconds post-infusion, equivalent to approximately one minute following injection of the contrast agent (col. 8 line 29). Prince ('767) also teaches the collection of image data post-infusion and following the time of elevated contrast absorption, which is equivalent to the flushing phase as described by the applicant (col. 4 line 59, Fig. 9). Prince ('767) shows that, for three patients, the flushing phase occurs at approximately 3 minutes post-infusion in the aorta

and IVC (Fig. 9), and it is obvious that the flushing phase for the rest of the vascular system occurs in the same time frame as for these two anatomical regions.

Additionally, the MRI scanner taught by Prince ('767), a 1.5T GE Signa v4.7, is implicitly capable of collecting data via FLASH sequences (col. 13, line 3).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system and method of Clarke (2000) to further include the contrast agent injection and imaging schemes and means of Prince ('767) in order to obtain more detailed and accurate information regarding plaque composition, and to thereby increase the accuracy with which such plaque is classified.

5. Claims 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (Identification of atherosclerotic plaque components using cluster analysis of multispectral MR images: comparison with histology. *Proc. SPIE Int. Soc. Opt. Eng.* 3978, 304-311. April 2000) in view of Prince (US Patent No. 5,579,767), further in view of Schneider (US Patent No. 6,415,048).

Clarke (2000), as previously modified by Prince ('767), substantially discloses all features of the present invention as previously presented. Both Clarke (2000) and Prince ('767) fail to teach means and steps for defining a same line in each of the three images and determining the respective intensity distributions along those lines.

In the same problem solving area, Schneider ('048) provides a method of medical image analysis in which a specific region of one image is compared to a specific region of another image, such as comparing activity in the brain over time (col. 1 lines 39-47). Schneider ('048) states "the term "region" represents individual segments of image data that is representative of a distinct process, event, part, object, place, or anatomical structure within the object being analyzed." Although Schneider ('048) does not discuss the use of a line as claimed in the instant application, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time of invention to choose a line as the shape of the image processing region.

Schneider ('048) specifically teaches that a processor compares the features of a classified region of a first image with a classified region of a reference image, wherein the reference image may be data from the same anatomical region (col. 4 lines 15-23). Schneider ('048) also teaches that the average intensity value of a region over time may be the comparison variable, and that the result of the comparison is displayed on a video screen (col. 4 lines 24-26 & lines 51-61).

It would have been obvious to one of ordinary skill in the art at the time of invention to further modify the method and system of Clarke (2000), previously modified by Prince ('767), to additionally include the image processing method and elements of Schneider ('048) to automatically analyze the intensity data of the acquired MR images over time, so as to minimize human error in the identification of plaque components.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Choudhury (2002) and Mofidi (2001) clearly demonstrate that it is known in the art that small vessel angiogenesis is a risk factor for plaque vulnerability. Cai (2002) teaches related means and steps for classifying atherosclerotic plaque via MR imaging.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha Solanki
Examiner – Art Unit 3737

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER